

Attorney Docket No. 06267.0085

Remarks

Claims 1-21 are pending in this application. Claims 1-10 and 13 have been amended for formalistic reasons to place the claims in condition for examination in the U.S. Patent and Trademark Office after entering the U.S. national stage. None of the amendments narrow the scope of the original claims.


Support for new claims 14-21 appears in the original claims.

If there is any fee due in connection with the filing of this Preliminary Amendment, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

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Appendix Detailing Amendments to Claims

1. (Amended) A pharmaceutical aqueous solution comprising levosimendan or a salt thereof as an active ingredient, the pH-value of the solution being lower than 5, [preferably about 4.5 or lower,] and optionally a solubility enhancing agent.

2. (Amended) A solution according to claim 1, the pH-value of the solution being in the range of from about 3 to about 4.2.

3. (Amended) An aqueous [Aqueous] intravenous infusion solution comprising levosimendan or a salt thereof as an active ingredient, the pH-value of the solution being lower than 5, [preferably about 4.5 or lower,] and optionally a solubility enhancing agent.

4. (Amended) A solution according to claim 3, the pH-value of the solution being in the range of from about 3 to about 4.2.

5. (Amended) A solution according to claim 3 [or 4], wherein the solubility enhancing agent is polyvinylpyrrolidone or ethanol.

6. (Amended) A pharmaceutical solution, [particularly an intravenous infusion concentrate,] comprising

(a) levosimendan or a pharmaceutically acceptable salt thereof as an active ingredient,

(b) a pharmaceutically acceptable organic solvent comprising ethanol,

(c) a stability enhancing amount of a pharmaceutically acceptable organic acid having pKa in the range of from 2 to 4, and optionally

(d) a water-solubility enhancing agent.

7. (Amended) A solution according to claim 6, wherein the amount of said solvent is 90-99.9% [, preferably 95-99.9%,] by weight of the solution.

8. (Amended) A solution according to claim 6 [or 7], wherein the amount of said organic acid is 0.005-2% [, preferably 0.01-1%,] by weight of the solution.

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9. (Amended) A solution according to claim 6 [any of claims 6-8], wherein the pharmaceutically acceptable organic acid is a 2-hydroxy alkanoic acid.

10. (Amended) A solution according to claim 9, wherein the pharmaceutically acceptable organic acid is citric acid, lactic acid, tartaric acid or malic acid.

13. (Amended) A solution according to claim 6, comprising
(a) levosimendan or a pharmaceutically acceptable salt thereof in an amount of 0.01-1.0% by weight,
(b) dehydrated ethanol in an amount of 95-99.5% by weight,
(c) citric acid in an amount of 0.03-0.6% by weight, and
(d) polyvinylpyrrolidone in an amount of 0.5-2% by weight.